



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q63988

Izumu SAITO, et al.

Appln. No.: 09/807,223

Group Art Unit: 1648

Confirmation No.: 5950

Examiner: Myron G. Hill

Filed: April 11, 2001

For: RECOMBINASE-EXPRESSING CELLS

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on
December 18, 2003:

REMARKS

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: Set of four draft claims (copy attached).
2. Identification of claims discussed: Claim 1.
3. Identification of art discussed: Hardy (WO 97/32481) and Wahl et al. (WO 92/15694).
4. Identification of principal proposed amendments: Applicants proposed to amend claim 1 to recite that the expression of recombinase Cre was "controlled expression in an FLP-dependent manner in the presence of recombinase FLP, which is provided by a recombinant

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adenovirus expressing recombinase FLP.” Applicants also proposed to amend claim 1 to recite that the cells are host cells for producing a recombinant adenovirus vector expressing a desired protein together with a helper virus.

5. Brief Identification of principal arguments: Applicants pointed out that the concept of *Hardy* and the concept of the present invention are entirely different, as is the problem to be solved. Applicants pointed out that the concept of *Hardy* is to avoid the harmful effect of Cre on the helper rAd which is that continuous expression of Cre results in deletion of loxP and thereby the packaging signal cannot be cut off. In contrast, the problem the present invention seeks to solve is the harmful effect of Cre on the Cre-expressing cell, which is that continuous expression of Cre results in reduction in the amount of expressed Cre due to cytotoxicity of Cre.

6. Indication of other pertinent matters discussed: none

7. Results of Interview: The examiner advised that he believed that claim 1 would be patentable if there is support in the specification for reciting “controlled expression.” However, the examiner advised that he would need to further study applicants’ arguments in more detail.

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It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

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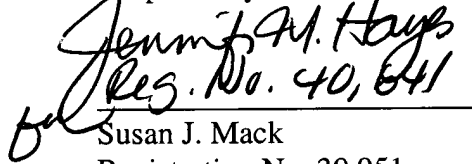
WASHINGTON OFFICE

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CUSTOMER NUMBER

Date: December 29, 2003

Respectfully submitted,


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